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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/825,379

04/14/2004

Hitoshi Hasegawa

P/3541-58

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2352 7590 04/16/2008  
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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/825,379	<b>Applicant(s)</b> HASEGAWA ET AL.	
	<b>Examiner</b> MONZER R. CHORBAJI	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/14/04;4/25/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

**This is a first action on the merits to the election/restriction answer received on 10/29/07**

1. Applicant's election without traverse of claims 1-2 and 9-12 in the reply filed on 10/29/2007 is acknowledged.

2. Claims 3-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/29/2007.

#### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by McPhail (WO 00/59553).

McPhail discloses a sterilization apparatus (figure 1), comprising:  
a container (figure 3:28) for sterilization including a containing section (inner surface of the lower half of cassette 28) in which a material to be sterilized is stored (page 1, lines 1-3), a connection section (unlabeled connector lines in fluid communication with cassette 28 in figure 9) which supplies/discharges a fluid (page 7, lines 6-10 and page 17, lines 9-12) to sterilize/cool the stored material with respect to the outside, and a blocking mechanism (figure 9:106 and 116)

which is disposed in the connection section and which can communicate to supply/discharge the fluid in a connected state of the connection section and which blocks off the supply/discharge of the fluid in a non-connected state of the connection section; a chamber (figure 1:4 and 6) in which the container for sterilization is stored to sterilize the material by steam having a high pressure and temperature; and fluid supply means (figure 8:112 and 120) capable of supplying at least one of a sterilization fluid to sterilize the material and a cooling fluid (figure 8:128 and page 17, lines 9-12) to cool the material via the connection section.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the

subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-2 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over McPhail (WO 00/59553) in view of Helmut (English Translation of DE 19724133).

Regarding claims 1, 9, McPhail teaches a sterilization apparatus (figure 1) comprising: a chamber (figure 1:4 and 6) in which a material to be sterilized (page 1, lines 1-3) is stored and a sterilizing step is performed to sterilize the material with steam of high temperature and high pressure (page 2, lines 1-12); a cooling mechanism (figure 8:128) which cools the material sterilized in the chamber, in a state isolated thermally (the materials within the cassette are at pressure and temperature values different from the inside of the chamber and are thermally isolated from the inside of the chamber by being placed within a sealed cassette) from the inside of the chamber; and a control section (page 10, lines 8-9) which drives the cooling mechanism (figure 8:128), thereby to cool the material. McPhail fails to disclose an opening/closing door mechanism.

Helmut discloses a compact steam sterilizer containing an opening/closing mechanism which facilitates easy loading and unloading of a sterilization container in the sterilizer upon opening and closing of the door. This mechanism for opening/closing

the cover (figure 1:3) for a steam sterilization vessel (figure 1:13), is essential to the compact sterilizer since, with such arrangement, the sterilization apparatus is able to placed onto existing laboratory furniture (Description section, page one, lines 10-11). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus in McPhail with an opening/closing mechanism as taught by Helmut, since with such arrangement the sterilization apparatus is able to placed onto laboratory furniture as described by Helmut (Description section, page one, lines 10-11).

As to claim 2, McPhail discloses a sterilization apparatus (figure 1) has a cooling mechanism (figure 8:128) and a control section (page 10, lines 8-9) and a cooling means (considered when the cassette is placed on the inner surface of door 6 in the open position within ambient environment away from the chamber). McPhail fails to teach that the cooling mechanism has moving means for moving the material out of the chamber. Helmut discloses a mechanism for opening/closing the cover (figure 1:3) for a steam sterilization vessel (figure 1:13) where the vessel is moved between two positions, the first position is into the apparatus and the second position (considered as the cooling position) is away from the apparatus (abstract section). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus in McPhail with opening/closing mechanism, since with such arrangement the sterilization apparatus allows for easy removal and loading of the sterilizer.

Regarding claim 12, McPhail discloses a sterilization apparatus (figure 1) having a control means (page 10, lines 8-9) and cooling mechanism (figure 8:128). As to the

means for control for opening the opening/closing means with end of the sterilization treatment, the device of McPhail is computer controlled in all other aspects and it would have been obvious to one having ordinary skill in the art to provide computer control of the door to prevent premature or unsafe opening of the sterilizer

**9.** Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over McPhail (WO 00/59553) as applied to claim 9 and further in view of Cope et al (U.S.P.N. 3,716,961).

McPhail discloses a sterilization apparatus, wherein the container (figure 3:28) for sterilization includes a sterilization case (cassette 28) and the sterilization case includes nozzles (page 10, lines 9-10 and unlabeled openings into cassette 28 that are connected to fluid and air sources as shown in figure 9) which is the connection section (unlabeled connector lines in fluid communication with cassette 28 in figure 9) and which supplies/discharges a fluid to sterilize and cool (figure 8:128 and page 17, lines 9-12) the stored material to be sterilized with respect to the outside. McPhail fails to teach providing a sterilization pack.

Cope discloses a sterilization pack with a nozzle (figure 4:17 and 13) for holding items so that articles can be handled and stored within the package for extended periods of time and still remain sterile (col.2, lines 30-32). Sterilant is injected into the pack through the nozzle. It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the apparatus in McPhail with the sterilization pack, so that articles can be handled and stored within the package for extended periods of time and still remain sterile as explained by Cope (col.2, lines 30-32). It would have

been obvious to modify the sterilization cassette of McPhail to connect the pack to the same nozzle inlets in the cassette in order to ensure that sterilant is adequately injected into the pack.

***Conclusion***

**10.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571)272-1271. The examiner can normally be reached on M-F 9:00-5:30.

**11.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**12.** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. R. C./

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797